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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,605	12/31/2001	George A. O'Toole	00246-266US1	1939

26161 7590 08/03/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,605	O'TOOLE ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/01, 7/01, 7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the Restriction requirement filed on May 10, 2004 is acknowledged. Applicant's election of Group VIII without traverse, claims 51-54 is acknowledged. Claims 1-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification Objections

2. The use of the trademarks has been noted in this application. See, for example page 36. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. The specification should be reviewed for trademarks and correction is required.

Claim Objection

3. Claims 54 is objected to for the following informality: Claim 54 recites "wherein in said bacteria is chosen from the group including: ..." Claim 54 should recite "selected from the group consisting of ...". Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 51-54 are rejected under 35 U.S.C. 102(a) as anticipated by Perez-Giraldo et al *(Journal of Antimicrobial Chemotherapy 1997, 39, 643-646).*

Claims 51-54 are drawn to a method of screening for compounds that modulate biofilm formation, said method comprising: a) exposing a bacterial culture to a test compound, such that at least one bacterial cell in said bacterial culture are contacted by said test compound and b) testing said bacterial culture for biofilm formation on an abiotic surface, wherein a decrease in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that inhibits biofilm formation and an increase in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that stimulates biofilm formation.

Perez-Giraldo et al teach a method of screening for compounds that modulate biofilm formation comprising exposing test compounds to *Staphylococcus epidermidis* (see the Abstract). Perez-Giraldo et al teach that the method comprises contacting the bacteria with the test compounds and determining the effect of the compounds on adhesion (pages 643-644). Perez-Giraldo et al et al teach that N-acetylcysteine inhibits

biofilm formation (see the Abstract). The claim limitation "wherein at least 5% of the bacterial cells contacted by the bacterial growth medium in said culture is contacted by said test compound" would be inherent in the teachings of the prior art. Perez-Giraldo et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claims 51-54 are rejected under 35 U.S.C. 102(b) as anticipated by Hussain et al *(J. Med Microbiology, Vol. 37, 1992, p. 62-69).*

Claims 51-54 are drawn to a method of screening for compounds that modulate biofilm formation, said method comprising: a) exposing a bacterial culture to a test compound, such that at least one bacterial cell in said bacterial culture are contacted by said test compound and b) testing said bacterial culture for biofilm formation on an abiotic surface, wherein a decrease in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that inhibits biofilm formation and an increase in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that stimulates biofilm formation.

Hussain et al teach a method of screening for compounds that modulate biofilm formation comprising exposing test compounds (e.g. antibacterial agents) to coagulase-negative staphylococci (CNS) (e.g. *Staphylococcus epidermidis*) (see the Abstract). Hussain et al teach that the method comprises contacting the bacteria with the test compounds and determining the effect of the compounds on adhesion (page 62-63). Hussain et al teach that several antibacterial compounds such as tunicamycin, chloramphenicol and 5-fluorouracil diminished biofilm formation (see the Abstract and Table IV, page 66). The claim limitation "wherein at least 5% of the bacterial cells contacted by the bacterial growth medium in said culture is contacted by said test compound" would be inherent in the teachings of the prior art. Hussain et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 51-54 are rejected under 35 U.S.C. 102(b) as anticipated by Blainey et al *(Biofouling 1991, Vo. 4, p. 309-318).*

Claims 51-54 are drawn to a method of screening for compounds that modulate biofilm formation, said method comprising: a) exposing a bacterial culture to a test compound, such that at least one bacterial cell in said bacterial culture are contacted by said test compound and b) testing said bacterial culture for biofilm formation on an abiotic surface wherein a decrease in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that inhibits biofilm formation and an increase in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that stimulates biofilm formation.

Blainey et al teach a method of screening for compounds that modulate biofilm formation comprising exposing test compounds (e.g. antibacterial agents) to *Pseudomonas* EK20 (see the Abstract). Blainey et al teach that the method comprises contacting the bacteria with the test compounds and determining the effect of the

compounds on adhesion (page 311). Blainey et al teach that "Synperonic F108 copolymer effectively inhibited the adhesion of a non-marine *Pseudomonas* EK20 to hydrophobic surfaces (see page 316). The claim limitation "wherein at least 5% of the bacterial cells contacted by the bacterial growth medium in said culture is contacted by said test compound" would be inherent in the teachings of the prior art. Blainey et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 51-54 are rejected under 35 U.S.C. 102(b) as anticipated by Anwar et al *(Antimicrobial Agents and Chemotherapy, June 1992, p. 1208-1214).*

Claims 51-54 are drawn to a method of screening for compounds that modulate biofilm formation, said method comprising: a) exposing a bacterial culture to a test compound, such that at least one bacterial cell in said bacterial culture are contacted by said test compound and b) testing said bacterial culture for biofilm formation on an abiotic surface wherein a decrease in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that inhibits biofilm formation and an increase in biofilm formation, relative to

biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that stimulates biofilm formation.

Anwar et al teach a method of screening for compounds that modulate biofilm formation comprising exposing test compounds (e.g. antibacterial agents) to *Pseudomonas aerginosa* (see the Abstract). Anwar et al teach that the method comprises contacting the bacteria with the test compounds and determining the effect of the compounds on adhesion (page 1209). Anwar et al teach that eradication of planktonic and young biofilm cells was observed after expose to tobramycin plus piperacillin (page 1210, 2nd column). The claim limitation "wherein at least 5% of the bacterial cells contacted by the bacterial growth medium in said culture is contacted by said test compound" would be inherent in the teachings of the prior art. Anwar et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 51-54 are rejected under 35 U.S.C. 102(b) as anticipated by Soboh et al *(Antimicrobial Agents and Chemotherapy, June 1995, p. 1281-1286).*

Claims 51-54 are drawn to a method of screening for compounds that modulate biofilm formation, said method comprising: a) exposing a bacterial culture to a test compound, such that at least one bacterial cell in said bacterial culture are contacted by said test compound and b) testing said bacterial culture for biofilm formation on an abiotic surface wherein a decrease in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that inhibits biofilm formation and an increase in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound indicates a compound that stimulates biofilm formation.

Soboh et al teach a method of screening for compounds that modulate biofilm formation comprising exposing test compounds (e.g. antibacterial agents) to *Pseudomonas aerginosa* (see the Abstract). Soboh et al teach that the method comprises contacting the bacteria with the test compounds and determining the effect of the compounds on adhesion (pages 1281-1282). Soboh et al teach that treatment with ciprofloxacin and protamine sulfate reduces the production of catheter-associated *Pseudomonas aeruginosa* biofilms (see the Title and the Abstract). The claim limitation "wherein at least 5% of the bacterial cells contacted by the bacterial growth medium in said culture is contacted by said test compound" would be inherent in the teachings of the prior art. Soboh et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
July 18, 2004

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600